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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,568	03/29/2004	Robert E. Carlson	14095.1US11	4101

23552 7590 07/27/2007  
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EXAMINER
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SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,568	<b>Applicant(s)</b> CARLSON, ROBERT E.	
	<b>Examiner</b> Mark L. Shibuya, Ph.D.	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-15 and 80-82 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 81 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-15 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/22/07 and 7/13/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Application 10813568, (20050037381 A1): Claims 1-3, 5-15, 80-82 are pending. Claims 4-9, 81 and 82 are withdrawn as drawn to a non-elected species. Claims 1-3, 10-15 and 80 are examined.

### ***Priority***

2. This application, 10/813,568, filed 03/29/2004, in the application data sheet, entered 3/29/2004, states that it is a continuation-in-part of 10/244,727, filed 9/16/2002, and is a continuation-in-part of PCT/US03/05328, filed 2/19/2003; and claims benefit of 60/459,062, filed 3/28/2003; 60/499,776, filed 9/3/2003; 60/499,975, filed 9/3/2003 and 60/526,511, filed 12/02/2003.

### ***Information Disclosure Statement***

3. The following Information Disclosure Statements (IDS), entered on the dates that follow, have been considered: 5/22/07 and 7/13/07. DE 19740263, (IDS filed 7/13/07), is considered insofar as it is the same as US 6,875,620. WO 00/13017, (IDS filed 7/13/07), is considered only to the extent of the included English language abstract.

***Withdrawn Claim Objections/Rejections***

4. The following objections/rejections to the claims are withdrawn in view of applicant's arguments and amendments to the claims.
5. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Korbel et al., J. Am. Chem. Soc. 2001, 12/20/2000, Vol. 123, 361-362, (IDS entered 8/10/2006).
7. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Maly et al., Proc. Natl. Acad. Sci. USA, 3/14/2000, Vol. 97, no. 6, pp. 2419-2424 (IDS entered 11/11/2003).
8. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al., J. Org. Chem. 1996, Vol. 61, pp. 6086-6087, (IDS entered 11/11/2003).

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9. Claims 1-3, 10 and 11-15 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung, Chemical Reviews, 1997, vol. 97, No. 2, pp. 473-488, (IDS entered 11/11/2003).

10. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch, US 6,083,763 A.

However, the rejection is maintained over claims 1-3, 10 and 11 and 80 as set forth below.

11. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/25910 A1, Stålberg.

However, the rejection is maintained over claims 1-3, 10 and 11 and 80 as set forth below.

12. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Lahiri et al., US 20030138853 A1.

13. Claims 1-3, 10-15 and 80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 85-105 of copending Application No. 10/244,727; claims 78-92 and 94-96 of copending Application No. 10/727,059; and claims 78, 79, 84, 90 and 96-102 of copending

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Application No. 10/706,505. This rejection is withdrawn in view of terminal disclaimers, filed 5/21/2007.

***New Claim Rejections - 35 USC § 112***

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for new matter.

The independent claims were amended in the paper entered 11/7/2006, to state the limitation "independently immobilizing the different building blocks to the support". This limitation may be construed as affecting the structure of the claimed array or receptor surface.

Applicant must explain where and how support may be found in the specification for this claim limitation.

***New Claim Rejections - 35 USC § 112, Second Paragraph***

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 80, and their dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making a heterogeneous building block array.

Claim 12, and its dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making a receptor surface.

Claim 14, and its dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making an artificial receptor.

Claim 1, in line 4, and claims 12, 14 and 80, recite the language "different building blocks", which renders the claims vague and indefinite, because it is unclear if

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this language refers to **"building blocks of different structures"**, as recited in the Specification, or merely refers to more than just a single building block.

Claim 1, in line 4, and claims 12, 14 and 80, recite the language "at least one of the building block is naïve", which renders the claims vague and indefinite, because it is unclear as to who is naïve. A building block is not naïve, and a quality of naïveté would not change the structure of the building block. Thus the limitation appears to depend, actually, upon the mental state of the practitioner. Thus, one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

***Maintained Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

18. Claims 1-3, 10 and 11 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch, US 6,083,763 A.

This rejection is maintained for the reasons of record as set forth in the previous Office action.

Balch, US 6,083,763 A, throughout the patent, and especially at col. 36, line 39- col. 37, line 50, Example IV, discloses methods of forming various biospecific molecules in a well, reading on a spot as claimed, among a plurality of wells on a plate, said plate reading on a solid support. Balch, at col. 37, lines 15-47, teaches, as an example, four



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different haptens immobilized at different biosites within a single well; and bispecific molecules, specific for one of the said haptens and for different analytes; wherein the hapten-bispecific molecules read on 2, 3, 4, 5, or 6 different building blocks. Balch teaches bispecific ligands that comprise antibodies, which absent evidence to the contrary, would comprise amino acids serine, threonine, and tyrosine (col. 37, lines 9-15). Balch teaches, at col. 9, lines 56-60, different substrates, including glass; at col. 3, lines 44-49, pin spotting; at e.g., col. 30, lines 37-62, teaches printing activated haptens onto an amino-silanized glass surface, reading on a functionalized lawn.

#### Response to Arguments

Applicant argues that Balch makes a plurality of homogeneous spots in a single well of a microtiter plate, which is not a heterogeneous spot or region.

Applicant's arguments, entered 5/15/2007, have been fully considered but they are not persuasive. The claims are accorded their broadest reasonable interpretation, consistent the specification. A single well of the microtiter plate describes a spot or region. Because there are a plurality of different molecules, which read on building blocks.

19. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by New et al., WO 01/01140 A1, (IDS entered 8/10/2006).

This rejection is maintained for the reasons of record as set forth in the previous Office action.

New et al., WO 01/01140 A1, throughout the publication, and at, e.g., pp. 15-19, 24-26, Examples 1 and 4, p. 15, teach conjugates of amino acids E, Y, Q, S and H, (p. 11), linked to lipids via a serine-glycine spacer, and reading on 2, 3, 4, 5, or 6 different building blocks (e.g., p. 18, p. 16), forming a supramolecular assembly such as a micelle, a lamellar structure, a liposome or other lipid structure (pp. 2-3, bridging paragraph), reading on spots, which are placed in glass vials and then transferred into microtiter plates, reading on arrays on solid supports (e.g., pp. 24-25), and on lawns forming a functionalized lawn coupling building blocks to and on the solid support, for the purpose of making artificial receptors. New et al., at, e.g., p. 2, teach conjugates comprising a head group and a tail group (reading on a linker), wherein the head groups are typically hydrophilic, and contain amino acids, including serine and tyrosine (p. 10-11, and Table 1) and the tail groups are typically hydrophobic, e.g., lipophilic, composed of hydrocarbon chains, halophilic, constructed of fluorocarbon or silane based, and forming a conjugate comprising and reading on a linker-framework-recognition elements, and wherein the linker has the formula  $(CH_2)_nC(O)-$  (p. 15, stating "[t]he structure of each conjugate is thus:  $NH_2$ -headgroup-spacer-amino acid ( $C_{14}$  side chain) -amino acid ( $C_{12}$  side chain)  $-CONH_2$ ").

#### Response to Arguments

Applicant argues that a liposome bound to a microtiter plate would represent a single building block, not a plurality of building blocks, bound to the plate. Applicant argues that building blocks are not coupled to a liposome.

Applicant argues that liposome are not mixed, each liposome conjugate is the same and are not a plurality of plurality of different building blocks bound to the plate.

Applicant argues that using a liposome is the same whether it is in solution or immobilized, so that plate bound liposomes are not in proximity to one another.

Applicant argues that New employs liposomes in solutions and test ligands bound to a support, which is different from the instant claimed invention.

Applicant's arguments, entered 5/15/2007, have been fully considered but they are not persuasive. The claims are accorded their broadest reasonable interpretation, consistent the specification.

New teaches a plurality of ligands on a single liposome, said single liposome reading on a solid support and the said plurality of ligands reading on a region that is a spot. The ligands are covalently bound to those portions of the molecule that are embedded in the liposome. The claims are drawn to making an array or receptor. Therefore, use of the test ligands in solution represent limitations not found in the claims.

***New Claim Rejections - 35 USC § 102***

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claims 1-3, 10-15 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Still, (IDS, filed 7/13/07).

Still, (IDS, filed 7/13/07), throughout the publication, and especially at p. 158, Fig. 1, disclose making heterogeneous building block arrays, by immobilizing tags (T<sub>1</sub>-T<sub>4</sub>) comprising applying building blocks that are tags. These combinations are naïve with respect to a test ligand, and they form a heterogeneous building block array.

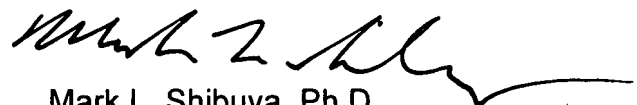
### ***Conclusion***

22. Claims 1-3, 10-15 and 80 are rejected.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.  
Primary Examiner  
Art Unit 1639